K022356

OCT 25 2002

11.0 510(k) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: not known

1. Name of Submitter, Contact Person and Date Summary Prepared:

Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, CA 92673
Phone: 949-240-5260
Fax: 949-940-7313

Contact Person: James A. Rybski, Ph.D.
Date Prepared: July 16, 2002

2. Device Name:

Trade/Proprietary Name:	Nichols Advantage® Chemiluminescence *Helicobacter pylori* IgG Antibodies Immunoassay
Common/Usual Name:	Anti-*H. pylori* IgG Assay
Classification Name:	*Campylobacter pylori* Serological Reagents

3. Predicate Device:

We claim substantial equivalence to the Orion Diagnostica Pyloriset® EIA-G Immunoassay (K971537, Cleared June 27, 1997).

4. Device Description:

The Nichols Advantage® *Helicobacter pylori* IgG Antibodies Assay is a two-site chemiluminescence assay for use with the Nichols Advantage® Specialty System.

Chemiluminescence

Nichols Institute Diagnostics utilizes chemiluminescence acridinium esters as the label in its specialty chemiluminescence system. Acridinium esters emit light upon treatment with hydrogen peroxide and an alkaline solution. The Trigger 1 solution contains hydrogen peroxide in diluted acid and Trigger 2 solution contains diluted sodium hydroxide. The system automatically injects Trigger solutions 1 and 2 into the

wells of the cuvette which oxidize the acridinium ester. The oxidized product is in an excited state. The subsequent return to ground state results in the emission of light, which is quantified in two seconds and is expressed in relative light units (RLU) by the integrated system luminometer.

Immunometric Assay

The Nichols Advantage® Anti-*H. pylori* IgG Assay is a two-site chemiluminescence immunoassay for the measurement of anti-*H. pylori* IgG in human serum. It utilizes an acridinium-ester-labeled mouse monoclonal anti-human IgG antibody and a biotinylated *H. pylori* antigen cocktail. The sample containing anti-*H. pylori* IgG antibodies is incubated with the biotinylated antigen cocktail and magnetic particles for 10 minutes at 37°C. Free, unbound biotinylated antigens and anti-*H. pylori* IgG antibodies are separated from the complex bound to the magnetic particles by aspiration of the reaction mixture and subsequent washing. Thereafter, acridinium-labeled anti-human IgG antibodies are added to the reaction mixture and a second 10 minute incubation follows creating the sandwich complex. Free, unbound acridinium-labeled anti-human IgG antibodies are separated from the complex bound to the magnetic particles by aspiration of the reaction mixture and subsequent washing. The wells containing the washed magnetic particles are transported into the system luminometer, which automatically injects Trigger 1 and Trigger 2, initiating the chemiluminescence reaction. The light is quantitated by the luminometer and expressed as RLU. The amount of bound-labeled antibody is directly proportional to the titer of anti-*H. pylori* IgG antibodies in the sample.

Automation

The Nichols Advantage Specialty System automatically handles sample dilution as well as sample and reagent additions, the temperature-controlled incubation, separation/washing step, and measurement of the light output. It calculates test results for controls and patient samples from the stored calibration curve, and generates a printed report, which includes patient information.

5. Intended Use:

The Nichols Advantage® Chemiluminescence *Helicobacter pylori* IgG Antibodies Immunoassay is intended for use with the Nichols Advantage® Specialty System for the qualitative determination of anti-*H. pylori* IgG antibodies in human serum to aid in the diagnosis of infection by *H. pylori*.

6. Comparison to predicate device:

The Nichols Advantage® Chemiluminescence *Helicobacter pylori* IgG Antibodies Immunoassay is substantially equivalent to other products in commercial distribution

for similar use. Most notably, it is substantially equivalent to the Orion Diagnostica Pyloriset® EIA-G Immunoassay.

The following tables compare the Nichols Advantage Chemiluminescence *Helicobacter pylori* IgG Antibodies Immunoassay with the predicate device, Orion Diagnostica's Pyloriset EIA-G Immunoassay.

Similarities:

- Intended Use: For the qualitative determination of anti-*H. pylori* IgG antibodies in human serum.
- Both assays use an *H. pylori* antigen cocktail to bind human anti-*H. pylori* antibodies.
- Both assays use human serum for the test sample.
- Both assays rely upon a sandwich formation by antibodies specific to human IgG to detect anti-*H. pylori* IgG antibodies.
- The sensitivity of both assays is sufficient to measure anti-*H. pylori* IgG antibody levels found in *Helicobacter pylori*-infected patients.

Differences:

Feature	Nichols Advantage® *Helicobacter pylori* IgG Antibodies Assay	Orion Diagnostica Pyloriset® EIA-G Immunoassay
Sample Size	Five (5) microliters	0.5 microliters* *100 microliters of a 1:201 dilution of the sample
Calibration	Two point calibration every two weeks (maximum) of stored working calibration curve; or when controls out of range.	Four point standard curve run with each assay.
Solid Phase	Streptavidin-coated magnetic particles. Streptavidin-biotin separation technology.	*Helicobacter pylori* antigen cocktail adsorbed to microtiter plate wells. Antibody sandwich-formation separation technology.
Incubation	Two Incubations: Total of 20 minutes at 37°C	Three Incubations: Total of 2 hr 30 min at room temperature (20-25°C)
Sensitivity	Less than or equal to 1:10 titer	Not described in the Directional Insert

Performance Characteristics:

FEATURE	Nichols Advantage® Chemiluminescence Anti-*H. pylori* IgG				Orion Diagnostica Pyloriset® EIA-G Immunoassay
Intra-Assay	Mean (titer)	SSD	%CV	n	None given
	34	2.9	8.5	20	
	241	11.3	4.7	20	
	1471	133.9	9.1	20	
Inter-Assay	Mean (titer)	SSD	%CV	n	None given
	26	6.0	23	20	
	238	38.1	16	20	
	2225	333.8	15	20	
Recovery	92% – 118%				None given
Parallelism	89% - 117%				None given
High Dose Hook Effect	Less Than 1:20,000 titer				None given
Method Comparison					
Range of Results	1:13 to 1:5526				1:97 to 1:9504
Concordance:	79.4%				
Percent Agreement Positive:	91.1% (95%CI: 87% to 95%)				
Percent Agreement Negative:	75.3% (95%CI: 70% to 81%)				

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 25 2002

James A. Rybski, Ph.D.
Manager, R&D Scientific and Clinical Affairs
Nichols Institute Diagnostics
1311 Calle Batido
San Clemente, California 92673

Re: k022356
Trade/Device Name: Nichols Advantage® Chemiluminescence *Helicobacter pylori* IgG Assay
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I
Product Code: LYR
Dated: September 30, 2002
Received: October 18, 2002

Dear Dr. Rybski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE STATEMENT

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510(k) Number (if known): K022356

Device Name: Nichols Advantage® Chemiluminescence *Helicobacter pylori* IgG Antibodies Immunoassay

Indications For Use: The Nichols Advantage® Chemiluminescence *Helicobacter pylori* IgG Antibodies Immunoassay is intended for use with the *Nichols Advantage®* Specialty System for the qualitative determination of anti-*H. pylori* IgG in human serum to aid in the diagnosis of infection by *H. pylori*.

Freddie M. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022356

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)